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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/598,297 | 08/23/2006 | Kyouichi Sekine | 20080-00006 | 2497 |

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| EXAMINER | |
|---|---|
| WALLENHORST, MAUREEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1797 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 06/22/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@jhkiplaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,297 | SEKINE ET AL. | |
| | Examiner | Art Unit | |
| | Maureen M. Wallenhorst | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/11/06 (2)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).

4. Claims 3-5, 7, 13, 15-17 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite since it is not clear whether the inspecting is performed by **comparing** the concentration of fat soluble vitamins and/or fat soluble food factors in the saliva of a subject after ingestion of a health supplement, drug or food to the concentration of the same fat soluble vitamins and/or fat soluble food factors before ingestion of the health supplement, drug or food by the subject, or by comparing the concentration of fat soluble vitamins and/or fat soluble food factors in the saliva of a subject after ingestion of a health supplement, drug or food to the concentration of the same fat soluble vitamins and/or fat soluble food factors measured in a control group ingesting no health supplement, drug or food. On lines 1-2 of claim 3, it is not

clear whether the phrase "is conducted on the basis of" refers to a comparison step as mentioned above. See this same problem in claim 5.

Claim 4 is indefinite since it is not clear how the detection of fat soluble vitamins or fat soluble food factors in saliva would serve to indicate how an administered therapeutic agent would serve to affect the biosynthesis or metabolism of the fat soluble vitamins or fat soluble food factors. Would an increase or decrease in the amount of the vitamins or food factors in the saliva of the subject after being administered a therapeutic agent in comparison to the amount of the same vitamins or food factors in the saliva of the subject before being administered the therapeutic agent serve as the means for determining the affect of the therapeutic agent on the biosynthesis and metabolism of the vitamins and/or food factors?

In part a) of claim 13, the phrases "the collected saliva", "the absorber with the absorbed saliva", "the preservative solution", and "the preserved absorber" lack antecedent basis since claim 13 depends from claim 1, and independent claim 1 does not positively recite the collection of saliva, an absorber for saliva or a preservative solution for any collected saliva.

Claim 15 is indefinite since it is not clear how drugs or health supplements are screened by simply analyzing fat soluble vitamins and/or fat soluble food factors in saliva, as recited in claim 1. Are the fat soluble vitamins and/or fat soluble food factors a component of the drugs or health supplements being screened? In addition, does the detection of the presence of the fat soluble vitamins and/or fat soluble food factors in saliva of a subject indicate that the drug or health supplement being screened has been successfully ingested into the body of the subject? See these same problems in claim 20.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 8-16 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Sekine et al (article from BioFactors, vol. 25, 2005, pages 205-211).

Sekine et al teach of a method for inspecting the presence and migration of the fat soluble food factor or supplement coenzyme Q10 (CoQ10) in the body of a subject by measuring this food factor in human saliva of the subject. The method comprises the steps of administering a supplement containing CoQ10 to subjects over a period of time, collecting whole saliva and parotid saliva samples from the subjects at baseline before the administration of the supplement and at various times after the administration of the supplement to the subjects by collecting the saliva samples with a device comprising an absorbent cotton swab and a preservative solution for the saliva samples, extracting the saliva samples from the preserved absorbent using ethanol,

using the resulting extract as an analysis sample to separate the fat soluble CoQ10 by high performance liquid chromatography (HPLC), and detecting the separated fat soluble CoQ10. The amount of CoQ10 in the saliva samples collected after administration of the supplement containing CoQ10 is compared to the amount of CoQ10 in the saliva samples collected at baseline before the administration of the supplement in order to assess the suitability of the ingestion or intake of the supplement by the subject, and to screen the supplement containing the CoQ10. Sekine et al teach that the levels of CoQ10 measured in parotid saliva samples have good correlation with plasma CoQ10 levels; however the measurement of CoQ10 in saliva samples is less invasive than the measurement of this fat soluble food factor in blood samples. Sekine et al teach that the noninvasive method for monitoring CoQ10 in the body of a subject by measuring its amount in saliva samples can be used for research purposes to screen supplements and to monitor the bioavailability of CoQ10 in patients or healthy people taking CoQ10. See the abstract and pages 206-207 and 210 of Sekine et al. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. Claims 1-3, 13-14 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lumikari et al (article submitted in the IDS received on October 11, 2006).

Lumikari et al teach of a method for inspecting the migration and presence of the fat soluble vitamin beta-carotene in the body of a subject by administering a supplement containing beta-carotene to a first group of subjects, administering a placebo containing no beta-carotene to a second group of subjects, collecting whole saliva and parotid saliva samples from both groups of subjects after administration of the supplement containing beta-carotene or the placebo,

extracting beta-carotene from the saliva samples with n-hexane, analyzing the resulting extract with high performance liquid chromatography (HPLC), and detecting the separated beta-carotene. The amount of beta-carotene measured in the saliva samples from the subjects administered the supplement containing beta-carotene is compared to the amount of beta-carotene measured in the saliva samples from the subjects administered the placebo in order to inspect the presence and migration of the beta-carotene in the body of the subjects administered the supplement containing beta-carotene. See the abstract and pages 172-173 of Lumikari et al.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4-5, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sekine et al. For a teaching of Sekine et al, see previous paragraphs in this Office action.

Sekine et al fail to teach that the measurement of CoQ10 in a saliva sample from a subject administered a supplement containing the fat soluble CoQ10 can be used to inspect the affect or assess the suitability of a dosage of a therapeutic agent having an affect on the

biosynthesis or metabolism of the fat soluble CoQ10. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Sekine et al for measuring CoQ10 in a saliva sample for such a purpose since Sekine et al teach that the presence and amount of CoQ10 in a saliva sample from a subject serves to indicate the presence and amount of CoQ10 in the body of the subject, and since a therapeutic agent might affect the presence and amount of CoQ10 in the body of a subject by altering its biosynthesis or metabolism, the measurement of the presence and amount of CoQ10 in a saliva sample from a subject administered the therapeutic agent would indicate whether the biosynthesis or metabolism of CoQ10 has been altered or changed by the therapeutic agent.

12. Claims 4-7, 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lumikari et al. For a teaching of Lumikari et al, see previous paragraphs in this Office action.

With regards to claims 4-5, 7 and 17, Lumikari et al fail to teach that the measurement of beta-carotene in a saliva sample from a subject administered a supplement containing the fat soluble beta-carotene can be used to inspect the affect or assess the suitability of a dosage of a therapeutic agent having an affect on the biosynthesis or metabolism of the fat soluble beta-carotene. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Lumikari et al for measuring beta-carotene in a saliva sample for such a purpose since Lumikari et al teach that the presence and amount of beta-carotene in a saliva sample from a subject serves to indicate the presence and amount of beta-carotene in the body of the subject, and since a therapeutic agent might affect the presence and amount of beta-carotene in the body of a subject by altering its biosynthesis or metabolism, the measurement of the presence and amount of beta-carotene in a saliva sample from a subject

administered the therapeutic agent would indicate whether the biosynthesis or metabolism of beta-carotene has been altered or changed by the therapeutic agent.

With regards to claims 6 and 16, Lumikari et al fail to teach that the measurement of beta-carotene in a saliva sample from a subject can be used to assess the suitability of ingestion of a supplement, drug or food containing the beta-carotene. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Lumikari et al for such a purpose since Lumikari et al teach that the amount of beta-carotene in saliva is raised in response to the intake of a supplement containing beta-carotene, so a person skilled in the art could easily determine whether the intake or the amount of intake of beta carotene in a supplement by a subject is adequate or not based on the measured beta carotene concentration in the saliva of the subject.

With regards to claims 15 and 20, Lumikari et al fail to teach that the measurement of beta-carotene in a saliva sample from a subject can be used to screen drugs or health supplements containing beta carotene. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Lumikari et al for such a purpose since Lumikari et al teach that beta carotene concentration in saliva is raised after a supplement containing beta carotene is administered to a subject, so a person skilled in the art would expect that when a medicine or health supplement containing beta carotene is ingested by a subject, its affect could easily be screened by measuring the concentration of beta carotene in a saliva sample from the subject.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Seymour who teaches of a device for collecting a saliva sample.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

June 17, 2010

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797